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No. 94-1971

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

SHILEY, Inc.; Hospital Products Group, Inc. (formerly Howmedica, Inc.); Pfizer, Inc.

Petitioners,

v.

NINA MICHAEL,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

In a case involving the unique circumstances of a defective artificial heart valve prone to catastrophic failure, whose marketing approval was withdrawn by the Food and Drug Administration at petitioners' request, was the court of appeals correct in holding that respondent's state-law personal-injury claims for fraud on her and her physicians and for breach of express written warranty were not preempted by a provision that bars states from establishing certain device "requirements" that are "different from, or in addition to" requirements "applicable to [a] device" under the Medical Device Amendments to the Food, Drug and Cosmetic Act?

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RESPONDENT'S BRIEF IN OPPOSITION

The case arises from injuries suffered by respondent Nina Michael as a result of the Bjork-Shiley Convexo-Concave heart valve ("C-C valve"). Respondent's doctors prescribed the C-C valve in reliance on petitioners' advertisements that deceived them into believing that the C-C valve was an appropriate treatment for respondent's ailment. After the valve had been implanted in respondent, evidence that the valve has a tendency to fracture while implanted in the chests of its patients, causing hundreds, if not thousands, of deaths and debilitating injuries, became public, as did the fact that petitioners concealed this evidence. After

respondent learned the truth about her C-C valve, her doctors took the unusual step of recommending that the C-C valve be explanted and replaced with a mechanical valve manufactured by a different company.[1]

In a narrow opinion, the contours of which were shaped by the unique facts of this case, the court of appeals held that the preemption provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), preempted all but two of respondent's state-law damages claims. The court held that respondent's claims based on petitioners' fraudulent promotion of the C-C valve to respondent's doctors and breach of express written warranty were not preempted because neither of those claims would establish state-law requirements "different from, or in addition to" MDA requirements, as 21 U.S.C. § 360k(a) demands. In finding these claims not to be preempted, the court of appeals faithfully applied the analysis set forth in this Court's recent decisions in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995), and *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992).

At bottom, petitioners' position is that, because the Food and Drug Administration ("FDA") gave them permission to market the C-C valve under the MDA's premarket approval provision, 21 U.S.C. § 360e, petitioners are immune from liability for respondent's breach of warranty claim created by petitioners' own contractual undertakings, and respondent's claim that she and her doctors were induced fraudulently to select petitioners' valve instead

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[1] Petitioner Shiley, Inc., the company that made the C-C valve, is a wholly-owned subsidiary of petitioner Pfizer, Inc. Petitioner Hospital Products Group, Inc. (formerly Howmedica, Inc.) is the division of Pfizer to which Shiley reported. For convenience, we generally refer to the companies collectively as "petitioners," although we recognized that each of them did not participate in every decision described below.

of a valve made by a competitor. The Third Circuit properly rejected the extreme approach put forward by petitioners, holding that neither the MDA nor its legislative history support the position that respondent's claims are preempted. As shown below, the decision of the court of appeals creates no conflict among the circuits and is fully consistent with the decisions of this Court. Therefore, review should be denied.

STATUTES AND REGULATIONS INVOLVED

The principal statutes and regulations involved in this case are reproduced in the appendix to this Opposition ("Resp. App.").

STATEMENT OF THE CASE

The history of the C-C valve is unique among medical devices. Yet, the petition creates the false impression that the decision of the court of appeals will have an important impact because the C-C valve was just another medical device that suffered from a few mechanical failures but generally complied with all legal requirements and caused little or no harm. Only by distorting the facts can petitioners hope to persuade this Court that the MDA's preemption provision should be applied to claims for deliberate deception of respondent's physicians outside of, and unrelated to, petitioners' FDA filings, and for breach of an express written warranty that petitioners voluntarily offered to respondent.

To show the unlikelihood that this case will ever be replicated, we first chronicle the unusual history of the C-C valve. Next, we discuss respondent's highly personal decision to remove the valve and replace it with a safer valve. Thereafter, we provide a brief description of respondent's lawsuit and the decisions below.

A. The History Of The C-C Valve

Mechanical heart valves, such as the C-C valve, are surgically implanted in individuals whose natural heart valves are not properly regulating their blood flow. The C-C valve consists of a metal disk inserted into a circular ring. The disk is attached to the ring by two sets of metal struts, one of which is integral to the ring and the other of which is welded to the ring. When the C-C valve is functioning, the blood flows from the heart through the ring, and the disk moves back and forth to regulate the flow. Unfortunately, because of serious, documented design and manufacturing defects in the C-C valve, the welded strut has a tendency — unique among mechanical heart valves — to fracture (2a). Fracture causes the disk eventually to break off from the ring, resulting in catastrophic failure and, in two out of three reported cases, patient death.[2]

In 1979, the FDA approved the C-C valve for commercial distribution. Although the FDA was aware at that time that one strut fracture had occurred during clinical trials, petitioners had described that incident as an "anomaly." House Report at 2, App. 380. In fact, however, petitioners failed to report that three strut fractures had occurred while petitioners' investigational device applications — a precursor to full commercial approval — were pending. House Report at 17-18, App. 395-96.

Moreover, 18 strut fractures had occurred in pre-clinical testing of the valve, the first occurring "as early as

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[2] "The Bjork-Shiley Heart Valve: 'Earn As You Learn,'" Report of the Subcommittee on Oversight and Investigations of the Energy and Commerce Committee of the U.S. House of Representatives (hereafter "House Report"), at 46, Third Circuit Appendix ("App.") 422.

May 1975."[3] Petitioners did not disclose these fractures until October 1985, after the devices had been implanted in almost all of its victims (including respondent), as part of a "data dump" on the FDA of more than 300 documents. Task Group Report at 24, App. 452. Shortly after the fractures began to occur, the device's principal designer, Dr. Viking Bjork, told petitioners' executives that the valve should no longer be marketed because it was "evident . . . that the manufacture of the prosthetic valve is not acceptable," and that the only solution was producing a valve without a welded strut. Shockingly, petitioners told Dr. Bjork not to publish his data concerning strut fractures, which would have alerted the medical community to the problem, because they expected "a few more" to occur. App. 548; *see* 33a.

In a 1983 paper written by Howmedica, petitioners belatedly conceded that their 29 millimeter valve — which has a particularly high fracture risk and is the type implanted in respondent — was poorly designed. House Report at 8, App. 386. Compounding the problems resulting from the valve's faulty design were petitioners' abysmal manufacturing processes. Howmedica's 1983 report found poor controls in the measurement of the C-C valves and in welding and little or no commitment to quality control. House Report at 8, App. 386. Howmedica further reported that Shiley's welding

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[3] *See* R.M. Johnson, *et al.*, "Report of the Shiley Task Group" (Dec. 1990) (hereafter "Task Group Report"), at 4-5, App. 432-33. The Task Group Report was based on a FDA study which concluded that petitioner "Shiley, Inc. has engaged in a continuing scheme to interrupt, deflect, and misdirect FDA's regulation of the Shiley Convexo-Concave heart valve." *Id.* at 2, App. 430. The Report also determined that it was likely that Shiley had engaged in criminal activity and urged that the case be transmitted to the Department of Justice for investigation by a grand jury. *Id.; see also id.* at 455 (discussing attempts to "obstruct justice" and "possibility of extreme criminal conduct").

practices were "out of control [and] not monitored," "that there [was] non uniformity of weld pattern," that poorly designed valves were being shipped for distribution, and that other significant problems existed. *Id.* Inspections of petitioners' manufacturing plants uncovered disgraceful conditions, including evidence of untrained welders, a lack of standard manufacturing procedures, and a failure to document device problems and failures. *See* House Report at 7-11, App. 387-91. Finally, as the Third Circuit explained in some detail, petitioners' management directed Shiley employees to cover up defects and strut cracks by re-welding weak struts and polishing out cracks, which further undermined the already precarious structural integrity of the valves, and deceived patients and their treating physicians about the true condition of the valves. JA 555-557, 613-17, 625-29, 635-36, *discussed in* 33a.

Despite their knowledge to the contrary, petitioners undertook a two-pronged effort throughout the 1980's to deceive the medical community — including specifically respondent's physicians (*see* 36a) — into believing that the C-C valve was safe. In "Dear Doctor" letters and other direct communications to physicians, including advertisements that were never reviewed by the FDA, House Report at 15-16, App. 393-94, petitioners misrepresented the true number of fractures and claimed that only a few fractures were expected in the future, when it had no basis for making such statements (33a). Second, petitioners told doctors falsely, with the intent to deceive, that the fracture problem, underreported as it was, was outweighed by an alleged thromboembolic advantage, *i.e.*, that the C-C valve experienced fewer blood clotting problems than did its

competitors. In fact, this so-called "advantage" did not exist. House Report at 15-17, App. 393-95.[4]

In February 1990, the Committee on Energy and Commerce of the U.S. House of Representatives held hearings on the C-C valve fiasco. The hearings made public the valve's design and manufacturing problems and petitioners' efforts to conceal them from the medical community. *See generally* House Report, App. 379-427. Less than a month later, on March 21, 1990, petitioners asked the FDA to withdraw its premarket approval, and the FDA did so nine days later (41a-42a).

Thus, despite petitioners' best efforts to prevent the medical community and patients from learning the truth, the C-C valve's high fracture rates gradually became known to physicians and the public. By early 1990, 389 fractures had been reported, 248 of which resulted in death. House Report at 45-46, App. 421-22. Moreover, because the signs and symptoms of imminent valve failure are similar to those of other cardiac problems, and because many patients with C-C valves died without autopsy, the actual number of fractures is estimated to be at least two to three times the number reported.[5]

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[4] In finding that respondent had produced sufficient evidence to proceed to trial on her fraud claim, the Third Circuit briefly summarized petitioners' deception with respect to its claim of thromboembolic advantage (33a). Above all else, it was the company's deception in this regard that kept the valve on the market, misled the medical community, and led to needless deaths and injuries. *See* Task Force Report at 15-18 (describing "the Thromboembolic Advantage Pretense"), App. 443-46.

[5] Through January 11, 1990, an additional 553 "hidden fractures" were estimated, although petitioners did not include these fractures in their "Dear Doctor" letters. House Report at 47-48, App. 423-24.

Then, a January 1992 study of over 2,300 Dutch C-C valve patients found that the cumulative incidence of strut fractures in the type of valve implanted in respondent is a dangerously high 4.2 percent, rising to 6.3 percent in individuals, such as respondent, under age 50.[6] Indeed, petitioners themselves wrote respondent's physician in June 1992, stating that the fracture risk for respondent's valve was an astounding 1.09 percent *per year*, and that her valve type had been recalled in 1983, less than one year *after* respondent received the implant. App. 675.

It is against this backdrop that Nina Michael decided, on the advice of her physicians, to have her valve surgically removed and replaced. Michael Dep. at 87-122, App. 238-43. One can only imagine the emotional distress faced by respondent in weighing the risk of valve replacement surgery against the risk of keeping the potentially deadly C-C valve in her chest. Although the petition (at 5-6) belittles respondent's claim on the ground that her valve never fractured, petitioners conveniently ignore the fact that, in 1992, they entered into a worldwide class action settlement in which, among other things, they agreed to pay for explantation surgeries for patients carrying high-risk C-C valves.[7]

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[6] Van Der Graff, *et al.*, *Risk of Strut Fracture of Bjork-Shiley Valves*, 339 The Lancet 257-61 (Feb. 1, 1992), *in* App. 669-73. The Dutch study concluded that prophylactic replacement of the C-C valve should be considered in patients, like respondent, with large 60 degree C-C mitral valves. *See* App. 477 (deposition testimony of respondent's physician indicating reliance on Dutch study).

[7] *See Bowling v. Pfizer*, 143 F.R.D. 141, 149, 166 (S.D. Ohio 1992), *appeal dismissed*, 14 F.3d 600 (6th Cir. 1993), *cert. denied*, 115 S. Ct. 294 (1994). In addition, on June 30, 1994, petitioners settled massive civil fraud claims under the False Claims Act with the United States government. Under that

(continued...)

B. Respondent's Lawsuit And The Decisions Below

In March 1993, respondent filed suit in Pennsylvania state court on theories of negligent manufacture and design, strict product liability, breach of implied warranty of merchantability, breach of an express warranty, and common-law fraud (on respondent, her doctors, and the FDA)(1a-2a). She sought recovery for the medical expenses and pain and suffering associated with removal of the C-C valve, for lost wages, and for emotional distress associated with her years of living with the threat that the valve inside her chest might fracture. Complaint, ¶¶ 30-33, 46-48, App. 22, 26-27; *see* 30a (noting causal relationship between breach of warranty and respondent's damages). Petitioners removed the suit to the United States District Court for the Eastern District of Pennsylvania based on diversity jurisdiction.

The district court dismissed respondent's claims on the ground that they were preempted by the MDA and that she had not produced sufficient evidence to state a claim under Pennsylvania law (39a-66a). The district court held that respondent's state-law claims would establish "requirements" "different from, or in addition to" federal requirements established when the FDA gave the C-C valve premarket approval in 1979. Therefore, the district court

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[7](...continued)
settlement, petitioners paid a $10.75 million fine, and agreed to reimburse the government for all past and future medical costs associated with C-C valve fractures and qualifying valve replacement surgeries which have been, or are in the future, incurred by Medicare, Medicaid, the Veterans Administration, and any other federal program. Settlement Agreement Between United States of America, and Shiley Incorporated and Pfizer, Inc., dated June 30, 1994.

held, her claims were preempted under 21 U.S.C. § 360k(a), the MDA's preemption provision.[8]

The court of appeals affirmed in part and reversed in part (1a-38a). Relying on its prior decision in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), and the decisions in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), and *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993), the Third Circuit affirmed the district court's preemption rulings as to negligence, strict liability, breach of implied warranty, and fraud on the FDA (13a-14a, 22a-24a). The Third Circuit reversed, however, the district court's rulings on express warranty and fraud on respondent's doctors, holding that the MDA did not preempt those claims (14a-21a, 24a-27a).

As to express warranty, the court relied on this Court's recent decisions in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), and in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995). In both of those cases, damages actions based on express warranty and contract theories were held not to be preempted because the duties that the plaintiffs were seeking to enforce were imposed not by "state law," as the preemption statute provided, but by agreement of the contracting parties (16a-18a). Thus, the court of appeals held that because respondent's "contract claim . . . is not state imposed — the *sine qua non* of preemption under § 360k," it is not preempted (21a).

As to the claim that petitioners fraudulently promoted the C-C valve to respondent's doctors, the court of appeals relied again on *Cipollone*, which held that claims grounded in fraud and misrepresentation were not preempted because they were not state-law "requirements" regarding the

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[8] 21 U.S.C. § 360k is reproduced in the appendix to this Opposition at Resp. App. 1a.

advertising and labeling of cigarettes, but rather concerned a *general* state-law duty not to deceive (25a). Because respondent's fraud claim concerned petitioners' deceptive use of "Dear Doctor" letters and medical journal advertisements, it was grounded in the general duty not to deceive, rather than in the "safety and effectiveness" of the device, as 21 U.S.C. § 360k(a)(2) requires (25a-26a). Similarly, the court of appeals held that respondent's fraud claim was not "different from or in addition to . . . any other matter included in a [MDA] requirement applicable to the device." 21 U.S.C. § 360k(a)(2). Petitioners' deceptive promotional activities were not, the Third Circuit held, subject to any FDA requirements or approvals and were voluntarily undertaken without significant FDA oversight (26a-27a). Thus, the fraud claim was not preempted.

The court of appeals then held, based on much of the evidence of deceit detailed above in Part A, that there was more than sufficient evidence under state law for the express warranty and fraud claims to proceed to trial (27a-37a). The court therefore remanded those claims for further proceedings (38a). Petitioners' request for rehearing and rehearing en banc was denied on March 7, 1995, with one judge voting to rehear the case (67a).

REASONS FOR DENYING THE WRIT

The decision of the court of appeals preempting some of respondent's personal-injury claims, but allowing others to go forward, is not a proper vehicle for considering whether the MDA preempts state-law damages claims. The decision below was a product of the unique factual setting here — petitioners' express written warranty and their direct communications to doctors in advertisements and promotional materials that were never submitted to the FDA and were unrelated to obtaining and maintaining premarket approval under the MDA. Further, there is no clear split among the federal appeals courts concerning the state-law damages

claims presented in the petition (fraud and express warranty), and the decision below is fully consistent with this Court's preemption decisions.

Moreover, as a result of petitioners' own request, the FDA withdrew its marketing approval of the valve prior to the filing of respondent's suit and, indeed, prior to the open-heart surgery to remove her fracture-prone valve, for which she seeks redress. Preemption surely should not apply where the FDA's regulatory approval is no longer in effect.

Finally, although not embraced in its entirety by the court of appeals, compelling evidence of Congressional intent demonstrates that 21 U.S.C. § 360k(a) was not meant to reach *any* state-law damages claims, including, therefore, the two claims which petitioners are challenging in this Court based on the fraud and breach of warranty that the evidence establishes here. This provides another ground for denying review, since, *a fortiori*, it confirms the correctness of the Third Circuit's decision on the fraud and express warranty claims.

A. The Decision Below Is Not In Conflict With Decisions Of This Court and There Is No Significant Conflict Of Lower Court Authority.

The court of appeals held that respondent's cause of action based on petitioners' fraudulent promotion of the C-C valve and her express warranty claim were not preempted. Ignoring the fact that the Third Circuit's decision is interlocutory, and thus not ordinarily subject to review in this Court, *see generally* R. Stern, et al., *Supreme Court Practice* 195-98 (7th ed. 1993); *see also Virginia Military Institute v. United States*, 113 S. Ct. 2431, 2432 (1993)(opinion of Scalia, J., respecting the denial of certiorari), petitioners argue that the ruling below warrants review because it is contrary to prior decisions of this Court and created a serious split in circuit court authority. As we now show, with

respect to both causes of action, petitioners are incorrect, and there is no need for review by this Court.

1. Fraudulent Promotion of the C-C Valve. In holding that the MDA does not preempt respondent's fraud claim, the court of appeals described in detail petitioners' systematic attempt to deceive respondent's doctors and others in the medical community about the risks and benefits of the C-C valve (31a-37a), which is the core of respondent's fraudulent promotion claim. Petitioners assert that the court of appeals' decision on this claim conflicts with the First Circuit's decision in *King*, 983 F.2d 1130, and the Fifth Circuit's decision in *Stamps*, 984 F.2d 1416. In fact, as the court of appeals held, its "conclusion does not conflict with the . . . determination in *King*" (27a), and the decision in *Stamps* is inapposite.

The fraud claim in *King* was expressly based on the "absence of warnings on the medical device" (27a). In the First Circuit's view, the claim was therefore a disguised failure-to-warn claim. Because that court held that a failure-to-warn claim was preempted as "different from, or in addition to" to the device's FDA-approved labeling, it held that the fraud claim was preempted as well. *King*, 983 F.2d at 1136; *see also id.* at 1139-40 (concurring opinion of Aldrich, J., and Campbell, J.).

In contrast, here, as the Third Circuit noted (27a), the fraud claim is premised solely on petitioners' false and misleading statements concerning the C-C valve. Respondent did not base this cause of action on a product liability defect or a failure-to-warn theory. Put simply, respondent's fraud allegations in this case have nothing to do with what should or should not have been on the C-C valve's label, and thus the Third Circuit's decision permitting that claim to proceed does not conflict with *King*. And, in *Stamps*, the Fifth Circuit did not even reach the plaintiff's fraud claim because the claim had not been properly pled in the complaint. 984 F.2d at 1422 n.5. Only by ignoring that crucial fact, and

equating a fraud claim with a duty-to-warn claim — which *Stamps* did find preempted — can petitioners make the attenuated argument that *Stamps* and the decision below are in conflict.

Nor are petitioners correct that the court of appeals misapplied this Court's case law in evaluating the fraud claim. The Third Circuit correctly interpreted *Cipollone*, which considered the preemptive effect of the Public Health Cigarette Smoking Act of 1969 on a variety of damages claims raised by a smoker who died from using the defendants' products. Section 5(b) of the Act provided that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." 112 S. Ct. at 2617. Section 4 of the Act mandated a specific warning for all cigarette packaging. *Id.* at 2616.

Cipollone held that because duty-to-warn claims could create state-imposed tort liability for failure to give a warning over and above the warning required by Congress, those claims were preempted. *Id.* at 2621. But other claims — fraudulent misrepresentation, conspiracy to misrepresent or conceal facts, and breach of warranty — were not preempted because, although they dealt with "smoking and health" in some sense, they were grounded in either a general tort duty not to deceive, or a contractual relationship between the parties. *Id.* at 2623-24 & n.27.

Similarly, as the Third Circuit held (25a), respondent's fraud claim does not, under 21 U.S.C. § 360k(a)(2), "relate to the safety and effectiveness of the device" or to any other MDA requirement, but is grounded, as in *Cipollone*, in a duty not to deceive. Thus, to prove fraud liability, respondent will have to show that she (or her doctors) used the C-C valve in justified reliance on petitioners' deceitful statements outside the labeling context — for example, their knowingly false statements regarding the fracture rate or

regarding thromboembolic advantage. Despite petitioners' protestations to the contrary, respondent's fraud claim is not premised on whether the valve was unsafe or ineffective or its warning labels inadequate.

Nor do the facts that the FDA has the power to require new device labeling to be submitted and to order manufacturers to notify the public of device problems mean that respondent's fraud claim related to other matters "applicable to the device under this chapter." 21 U.S.C. § 360k(a)(2); *see* Pet. 18. The FDA has never, to respondent's knowledge, pre-approved magazine advertisements as device labeling, and nothing in the regulations cited by petitioners suggests otherwise. Pet. 18-19. Accordingly, the FDA did not require petitioners to submit copies of proposed advertising of the C-C valve. And no such MDA requirements "*applicable* to the device" concern petitioners' alleged deceit, as is necessary for preemption under 21 U.S.C. § 360k(a), as the Third Circuit correctly held (26a-27a). As to the FDA's power to require notification to doctors and patients under 21 U.S.C. § 360h(a), even assuming that power has any preemptive effect — which, in our view, it does not — it relates to a state-law duty-to-warn claim, not to whether petitioners affirmatively committed fraud on the medical community by issuing false and misleading advertisements and letters.[9]

In an effort to escape the holding of *Cipollone*, petitioners claim that the court of appeals should have relied on purportedly broader preemption holdings that construe the statutory term "relate to" because that term is used in

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[9] Petitioners reliance on 21 U.S.C. § 360h(a) is disingenuous, since they do not cite § 360h*(d)*. Under that provision, even when the FDA orders a manufacturer to provide notification under § 360h(a), such an order "shall not relieve any person from liability under Federal *or State law*" (emphasis added). *See infra* at 24-25 (discussing § 360h(d) in more detail).

§ 360k(a). Pet. 13-17 (*citing, e.g., Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990)). But as explained above, respondent's fraud claim does not "relate to" any MDA requirements, but is grounded in petitioners' deceptive conduct. To be sure, the words "relate to" can be stretched to establish a connection between any two things. But as this Court recently held in a unanimous decision involving the same ERISA preemption provision construed in *Ingersoll-Rand*, in light of the strong presumption against preemption, "[i]f 'relate to' were taken to extend to the fullest stretch of its indeterminacy, then for all practical purposes preemption would never run its course ... ." *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995)(state hospital pricing statute that applies to health insurance generally, including ERISA plans, not "relate[d] to" those plans and thus not preempted).

Finally, quite apart from the "relate to" language of § 360k(a)(2), in order to be preempted, the fraud claim must *also* be "different from, or in addition to" an FDA requirement. 21 U.S.C. § 360k(a)(1). On this score, petitioners argue only that a damages award based on fraud would somehow be different from, or in addition to, the FDA's device labeling provision and 21 U.S.C. § 360h(a). Pet. 19-20. Again, as discussed above, the FDA's regulatory authority over labels and the *potential* for FDA to require petitioners to issue a public notification are not anti-fraud provisions and have no bearing on whether petitioners affirmatively defrauded the medical community and heart valve patients such as respondent.

2. Breach of Express Warranty. Petitioners argue that the decision below conflicts with the First Circuit's decision in *King*, which preempted an express warranty claim. The court of appeals effectively demonstrated that its decision does not conflict with *King*. Since *King* did not describe the specific language of the warranty at issue there (19a), it is unclear whether the warranty was actually required by the MDA or rather, as here, a voluntary

undertaking, warranting on the device's package that "reasonable care has been used in the manufacture of this device" (6a). This point is potentially dispositive since, under *Cipollone*, such private contractual undertakings are not state-imposed "requirements" that trigger preemption. *See* 17a.

Moreover, as the court of appeals noted (21a), even if placing a warranty on the valve's packaging transformed the warranty into an MDA requirement, rather than a voluntarily undertaken obligation of the warrantor (as *Cipollone* teaches), a state-law breach of warranty finding would not be "different from, or in addition to" any MDA requirement; it would be vindication of that requirement. *See* 21 C.F.R. 808.1(d)(2)(MDA "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the Act"). *King* also did not consider this alternative basis for finding that the express warranty claim was not preempted.[10]

Petitioners also assert that the court of appeals misapplied *Cipollone*'s express warranty holding. However, as in *Cipollone*, the express warranty claim here was not imposed by state law, or even by the FDA, but was voluntarily placed on the C-C valve's packaging "*by the warrantor[s]*," *i.e.*, petitioners. *Cipollone*, 112 S. Ct. at 2622 (emphasis added). Furthermore, in *Cipollone*,

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[10] For the same reasons, the express warranty holding in *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995), is not in conflict with the decision below. Indeed, *Martello* did not separately evaluate any of the plaintiff's causes of action, and cited with approval a decision which held that a state-law claim that seeks only to vindicate federal regulatory requirements is not preempted. *Id.* at 1169 (*citing Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993)). This Court denied certiorari in *Martello* after the filing of the petition here.

"statements made in respondents' advertising," *id.* at 2622, created non-preempted, enforceable warranties, even though they were displayed in the very advertisements on which, in 1972, the Federal Trade Commission required that the federally-mandated warning be placed. *Id.* at 2617; *see id.* at 2622 ("That the terms of the warranty may have been set forth in [regulated] advertisements rather than in a separate document is irrelevant").[11]

This Court's decision last Term in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995), also supports the Third Circuit's express warranty ruling. *Wolens* held that contract claims grounded in promises made by airlines in their frequent flyer programs are not preempted by a provision in the Airline Deregulation Act that preempts state laws "related to a price, route, or service of an air carrier . . . ." *See id.* at 821 n.1. As in *Cipollone*, the Court held that contractual obligations undertaken voluntarily — like petitioners' voluntary representation that it used "reasonable care" in the manufacture of the C-C valve — were not imposed by state law, but by the parties to the contract. *Wolens*, 115 S. Ct. at 824. As in *Wolens*, respondent here seeks to do no more than hold petitioners to their bargain, "with no enlargement or enhancement based on state laws or policies external to the agreement." *Id.* While petitioners

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[11] Petitioners' new-found claim that the Third Circuit misunderstood *Cipollone* is more than a little ironic. In the district court, petitioners had explicitly conceded that the express warranty claim was not preempted because of the holding in *Cipollone*, and thus did *not* move for summary judgment on that basis. Defendants' Motion for Partial Summary Judgment Based on Federal Preemption, at 19 n.17, App. 70. Accordingly, the district court did not specifically consider whether respondent's express warranty claim was preempted. Nevertheless, the court of appeals held that the district court had preempted all of respondent's claims and addressed the express warranty claim (14a).

are correct that their manufacturing processes might come into play in assessing the express warranty claim, the Court in *Wolens* acknowledged that airline "rates and services" — the very topics of the relevant preemption provision — would necessarily be at issue in the breach of contract suit. *Id.* But because "[a] remedy confined to a contract's terms simply holds parties to their agreements," the express warranty claim was not preempted there. *Id.* For the same reason, the express warranty claim is not preempted here, and the court of appeals' decision was correct.

B. The Unique Circumstances of Respondent's Case and the Regulatory History of the C-C Valve Make This Case A Poor Vehicle For Considering The General Scope Of MDA Preemption.

As noted above, this case turns on unique circumstances, and is not a precedent-setting ruling on the general scope of MDA preemption. As a so-called Class III medical device (*see* 3a-4a), the C-C valve was the first device after the passage of the MDA for which a medical device manufacturer sought and received premarket approval from the FDA. At that time, the agency had not formulated any specific internal rules for heart valves and had not yet established formal procedures for considering premarket approval applications (*see* 4a). Petitioners took advantage of this regulatory disarray to fraudulently promote their product during and after the FDA approval process to doctors, for whom petitioners were the sole source of information on the C-C valve (5a). Because the FDA's premarket approval procedures are now in place, it is not nearly as likely that the extreme deception of the medical community that occurred with the C-C valve — which is the basis for one of respondent's non-preempted claims — will recur in the future.

Further, as part of its marketing scheme, petitioners offered an unusual written warranty that is central to the

court of appeals' other holding concerning respondent's express warranty claim (14a-22a). That type of warranty is not likely to be offered again, which also undermines the general significance of the court of appeals' ruling.

Moreover, a ruling here would have little practical consequence for other C-C valve victims, many of whom have died or resolved their claims in a world-wide class action settlement. *See supra* at 8 & note 7. Accordingly, the vast majority of future fracture and reoperation claims are governed by that settlement and thus unaffected by the decision below. *Bowling*, 143 F.R.D. at 148-50 (describing relief in detail).

Finally, after petitioners' fraud was exposed, they asked the FDA to withdraw premarket approval of the C-C valve. In requesting the withdrawal, petitioners promised that they would "not at any time reintroduce th[eir] product into commerce in the U.S. or overseas." App. 836. On March 30, 1990, the FDA accepted the withdrawal. App. 838, *see* 41a-42a.[12] Because of this unique regulatory chronology, there is no possibility that the C-C valve will be implanted in another unsuspecting patient. In light of the overwhelming

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[12] One court has held that the withdrawal of the C-C valve's pre-market approval vitiates any preemptive effect 21 U.S.C. § 360k(a) may have had on the fraud claim of a C-C valve victim. Order and Opinion Re Federal Preemption, *Khan v. Shiley*, No. 50 52 48 (Orange Cty. Sup. Ct. July 9, 1993), *in* App. 98. The district court disagreed (50a n.11). *But see Freightliner Corp. v. Myrick*, 115 S. Ct. 1483 (1995)(no preemption where federal highway safety standard no longer in effect).

The question whether preemption is applicable under the MDA where there is no extant premarket approval is squarely presented in *Kemp v. Pfizer, Inc.*, No. 94-1502 (6th Cir.), a case in which the plaintiff died when the C-C valve fractured. *Kemp* is fully briefed and will be argued to the Sixth Circuit on September 28, 1995.

evidence of petitioners' fraud and misrepresentation (27a-37a), which further distinguishes this case from a run-of-the-mill product liability action, this Court should deny review and await an MDA preemption case which presents personal-injury claims that are not clouded, as the claims here are, by the FDA's withdrawal of the device's premarket approval.

C. Because Congress Did Not Intend The MDA To Preempt Any State-Law Damages Claims, The Third Circuit's Rulings On The Fraud And Express Warranty Claims Are Plainly Correct.

Because of its prior holding in *Gile v. Optical Radiation Corp.*, 22 F.3d 540, the court of appeals was required to assume that, in enacting the MDA, Congress intended to preempt some state-law damages actions. However, as we now show, that assumption is not correct, which provides further support for the Third Circuit's decision that two of respondent's claims are not preempted.

First, the MDA's preemption provision, 21 U.S.C. § 360k(a), does not apply to all "State law" — language which *Cipollone* considered important and which reasonably may be construed to include common law. Rather, § 360k(a) states that "[n]o State or political subdivision of a State may establish or continue in effect" certain device "requirements." To equate a jury award or a court adjudication of a common law claim with a "State . . . establish[ing] or continu[ing] in effect" a device "requirement" strains ordinary English usage beyond the breaking point. *See Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 210, 204 Ill. Dec. 744 (Ill. App. 1994).[13]

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[13] Several federal appellate courts, in addition to the Third Circuit, have held that § 360k(a) can preempt some common law claims. *See, e.g., King*, 983 F.2d 1130; *Stamps*, 984 F.2d 1416; (continued...)

Second, whether the word "requirement" covers damages actions depends on the word's context in the statute at issue. *See Brown v. Gardner*, 115 S. Ct. 552, 555 (1994) ("a word is known by the company it keeps") (citing *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961)). Section 360k(a) uses "requirement" three times:

> [N]o state . . . may establish or continue in effect with respect to a device intended for human use any *requirement* (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to a device under this chapter (emphasis added).

The latter two uses of "requirement" in § 360k(a) are unambiguous references to the statutory and regulatory requirements imposed under the MDA, *see, e.g.*, 21 U.S.C. § 360e(d)(2)(A),(B) (premarket approval labeling requirements), not references to damages remedies or to the common law. *See Haudrich*, 642 N.E.2d at 209-10; Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 926 (1995).

The first use of "requirement" in § 360k(a), referring to actions of states and their political subdivisions that may be preempted by the MDA, is stated identically to the latter

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[13](...continued)
Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992). But as one commentator stated, this line of "cases appear to ignore both the explicit language of the MDA and the clear legislative history leading up to that Act." Javitt, *I've Got You Under My Skin — And I Can't Get Redress: An Analysis of Recent Case Law Addressing Preemption of Manufacturer Liability for Class III Medical Devices*, 49 Food & Drug L.J. 553, 559 (1994).

two, and it also makes no reference to damages actions or the common law. Thus, there is no indication that Congress meant the term "requirement" to be interpreted in two different ways within a single sentence, which would be necessary to overcome "the basic canon of statutory construction . . . that identical terms within an Act bear the same meaning." *Reno v. Koray*, 115 S. Ct. 2021, 2026 (1995)(internal quotation and citation omitted). Accordingly, the types of state-law "requirements" referred to at the beginning of § 360k(a) are the same types of federal-law "requirements" referred to at the end of § 360k(a) — that is, statutes, regulations, and ordinances concerning devices, not damages remedies.

Third, the plain meaning of § 360k(a) is confirmed by its legislative history. In enacting the MDA and its preemption provision, Congress made no mention whatsoever of an intent to preempt state common-law claims. *See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. at 1681 (no preemption under ERISA of hospital cost pricing where "there is not so much as a hint in ERISA's legislative history" that Congress intended such preemption). Rather, the MDA's legislative history refers solely to the potential for preemption of state and local laws and regulations addressed specifically to medical devices. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 4, 45-46 (1976).

Fourth, subsection (b) of 21 U.S.C. § 360k — mentioned nowhere in the petition — further undermines any claim that subsection (a) preempts damages claims. Subsection (b) allows States or their political subdivisions to apply to the FDA for exemptions in order to maintain "requirements" that would otherwise be preempted under subsection (a). The language of subsection (b) parallels that of subsection (a) and allows applications only from "State or political subdivisions" to exempt "requirements" "applicable to a device for human use." The legislative history of subsection (b) is clear that exemptions may be sought for

anything preempted under subsection (a), yet that history refers only to "regulation[s]" and other positive enactments issued pursuant to state law. H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). Moreover, the FDA's regulations construing subsection (b) begin by stating that a "State or political subdivision may apply . . . for an exemption from any requirement it has *enacted* . . . ." 21 C.F.R. § 808.20(a) (emphasis added). The term "enacted" obviously does not refer to jury awards or common law claims.[14]

Fifth, the MDA contains another provision that, consistent with the presumption against preemption, assumes that state-law damages actions will co-exist with federal regulation of medical devices. Under 21 U.S.C. § 360h(a), (b), and (c), the FDA has the power to notify the public and health professionals of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds and reimbursements with respect to such devices. Petitioners, however, while relying on § 360h(a), Pet. 2, 18, 20, ignore subsection (d) of § 360h, which is "[o]f vast significance" to the preemption analysis. *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994). That subsection, entitled "Effect on Other Liability," provides:

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[14] *See also* 21 C.F.R. § 808.20(c)(1) (requiring state or locality seeking exemption to submit "any statute, rule, regulation or ordinance" for which exemption is sought); 21 C.F.R. § 808.1(d)(6)(ii)(in assessing whether a state or local requirement is preempted, "the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the *statute*")(emphasis added); *cf. New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 384 A.2d 795, 813-14 (1978)(existence of § 360k(b) is strong evidence of narrow preemptive scope of § 360k(a)).

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360h(d)(Resp. App. 2a). Thus, section 360h(d) "specifically contemplates [actions under] state law [for] liability and damages" against manufacturers of medical devices, and "unambiguously prohibits a finding of liability pursuant to section [360h](b) and (c) from shielding a defendant from state liability and damages. . . ." *Mulligan*, 850 F. Supp. at 636; *see* 18a (Congress "gave indications in 21 U.S.C. § 360h that at least some common law remedies would remain in conjunction with FDA regulation"); *cf. Lohr v. Medtronic, Inc.*, 1995 WL 360472, *5 (11th Cir. July 3, 1995).[15]

Sixth, the FDA — the agency charged by Congress with interpreting the MDA and implementing its preemption provision — has reasonably construed the MDA not to preempt common-law claims. For instance, FDA regulations are clear that the MDA preempts only device-specific requirements, not *general* duties such as those created by the common law:

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[15] In *Lohr*, the Eleventh Circuit found that the plaintiffs' duty-to-warn and manufacturing defect claims were preempted by the MDA, but that their design defect claims were not preempted. 1995 WL 360472, *11-*13, *15-*16. Because *Lohr* did not involve express warranty or fraud claims, *Lohr* is not in conflict with the rulings of the court of appeals for which review is sought in the petition.

> State or local requirements are preempted only where the Food and Drug Administration has established specific counterpart requirements applicable to a particular device under the act, thereby making any existing state or local requirement different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(Resp. App. 3a). FDA regulations further state that section 360k(a)

> does not preempt State or local requirements of *general applicability* where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (warranty of fitness)) or to unfair trade practices in which the requirements are not limited to devices . . . .

21 C.F.R. § 808.1(d)(1)(emphasis added)(Resp. App. 3a). Here, of course, respondent's claims are based on state-law duties, such as the general duty not to deceive and the duty imposed by state contract law, that "relate[] . . . to other products in addition to devices . . . . " Although not relied on by the Third Circuit, the views of the FDA provide further support for a narrow reading of 21 U.S.C. § 360k(a).[16]

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[16] Consistent with the FDA's regulatory stance, the Justice Department recently filed amicus briefs on behalf of the FDA, stating that premarket approval requirements are not "specific requirements" with respect to a device and, therefore, do not preempt state-law damages claims, Brief for United States as Amicus Curiae in *Talbott v. Bard*, No. 94-1951 (1st Cir.), at 14 n.5, 25-26 n.7, and that express warranty claims are not preempted (continued...)

For all these additional reasons, the decision of the court of appeals is correct as to the fraud and express warranty claims and review should not be granted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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Attorney for Respondent

August 2, 1995

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[16](...continued)
by 21 U.S.C. § 360k(a). Brief for the Food and Drug Administration as Amicus Curiae in *Duvall v. Bristol-Myers Squibb Co.*, No. 94-1520 (4th Cir.), at 11-22.

The FDA has also issued regulatory pronouncements stating that state-law judicial remedies, such as product liability claims, are not preempted by 21 U.S.C. § 360k(a). *See* Advisory Opinion of FDA's Associate Commissioner for Regulatory Affairs, dated Mar. 8, 1984 (Resp. App. 4a-6a), *in* App. 955-59; Letter from Chief of FDA's Regulatory Staff, dated Feb. 2, 1987 ("FDA believes that section 521 [§ 360k(a)] does not preempt general product liability requirements")(Resp. App. 7a), *in* App. 961-63.

PRINCIPAL STATUTORY PROVISIONS INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

* * *

21 U.S.C. § 360h(d) provides:

Effect on Other Liability

Compliance with an order [requiring a manufacturer to repair, replace, or provide reimbursement for expenses relating to an unsafe device] issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

PRINCIPAL REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regualtion of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different

from, or in addition to, any requirement applicable to such device under any rpovision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to adevice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in National Women's Health Network, et. al. v. A.H. Robins Company, Inc., No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injuctive remedies. This advisory opinion does not address

the merits of the application of such remedies in any action filed by the network in the State of Massachussets or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures